PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
RFW/C70501		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP 03/02876	18.03.2003	20.03.2002
International Patent Classification (IPC) or both national classification and IPC		
A61M5/00		
Applicant		
GLAXO GROUP LIMITED ET AL.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
06.10.2003	15.09.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840	Authorized Officer Schultz, O Telephone No. +49 30 25901-566

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/02876

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-20 as originally filed

Claims, Numbers

1-30 as originally filed

Drawings, Sheets

1/9-9/9 as originally filed

2. With regard to the **language,** all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

   ☐ restricted the claims.

   ☒ paid additional fees.

   ☐ paid additional fees under protest.

   ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

   ☒ all parts.

   ☐ the parts relating to claims Nos. .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	5,14-18,22,27-29
	No:	Claims	1-4,6-13,19-21,23-26,30
Inventive step (IS)	Yes:	Claims	5,14-18,22,27-29
	No:	Claims	1-4,6-13,19-21,23-26,30
Industrial applicability (IA)	Yes:	Claims	1-30
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

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A Invention I (Claims 1-18):

1 Reference is made to the following documents (D):

D1: WO 96/24398 A,
D2: US 2001/031945 A1,
D3: WO 97/37705 A.

2 The present application does not meet the requirements of Article 33(2) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT. The reasons are as follows:

2.1 The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (the references in parentheses applying to this document):

"A casing (see fig. 1, reference sign 111,110) for an injection device (see fig. 1, reference signs 105,114,119,102,103,...) of the type which comprises

a cartridge (see fig. 1, reference sign 102) containing a medicament (see fig. 1, reference sign 101) for injection and having a orifice (see fig. 1, reference sign 103) at one end thereof through which the medicament (see fig. 1, reference sign 101) may be driven for injection through a patient's skin (see fig. 3, reference sign 122),

drive means (see fig. 1, reference sign 119,118) for driving the medicament (see fig. 1, reference sign 101) through the patient's skin (see fig. 3, reference sign 122),

a trigger means (see fig. 1, reference sign 114) operable to cause the drive means (see fig. 1, reference sign 119,118) to act,

a safety means (see fig. 1, the protrusion of the element 121 which is directed to the inside of the casing and which secures the trigger means 114) which in a first configuration (see fig. 1) prevents the drive means (see fig. 1, reference sign 119,118) from acting and in a second configuration (see fig. 2) allows the drive means (see fig. 1, reference sign 119,118) to act,

wherein

the casing (see fig. 1, reference sign 111,110) is adapted to enclose the

device (see fig. 1, reference signs 105,114,119,102,103,...),

and the casing (see fig. 1, reference sign 111,110) incorporates an actuator means (see fig. 1, reference sign 121, it is the part which protrudes to the outside of the casing) by which the safety means (see fig. 1, the protrusion of the element 121 which is directed to the inside of the casing and which secures the trigger means 114) of an injection device (see fig. 1, reference signs 105,114,119,102,103,...) enclosed therein can be brought from its first configuration (see fig. 1) into its second configuration (see fig. 3)".

2.2 Moreover, document D2 also discloses on its figures 4 and 5 all the features of claim 1, namely:
"a casing" (see fig. 4 and 5, reference signs 44 and 46);
"an injection device" (see fig. 4 and 5);
"a cartridge" (see fig. 4 and 5, reference sign 23);
"a medicament for injection" (see fig. 4 and 5, reference signs 12);
"an orifice" (see fig. 5, reference sign 20);
"drive means" (see fig. 4 and 5, reference signs 37,38,42);
"trigger means" (see fig. 4 and 5, reference sign 36);
"safety means" (see fig. 4 and 5, the inner surface of the casing which covers the trigger means prevents the trigger means from being pushed in the first configuration);
"actuator means" (see fig. 4 and 5, it is the part of the casing which is suitable to be gripped pushed by the hand of an users to bring the safety means from its first configuration (see fig. 4) into its second configuration (see fig. 5));
"first configuration" (see fig. 4);
"second configuration" (see fig. 5).

2.3 Furthermore, document D3 also discloses on its figures 1 to 2B all the features of claim 1.

3 Dependent claims 2-4 and 6-13 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT with respect to novelty, the reasons being as follows:

3.1 Document D1 discloses all the features of dependent claims 2,3 and 6 to 11, see for example:
- figures 1 and 2 (relevant to claim 2,3,6);

- figures 2 (relevant to claim 7)
  It is noted that the "retaining means" is designed into the hinge of the actuator. Obviously, the retaining means (hinge) is a material which is not resilient, so that once the actuator is pulled to bring the safety means into its second configuration the actuator stays there (see fig. 2,3,4);
- figures 1-4 (relevant to claim 8);
- figures 1,2 (relevant to claim 9,10);
- figures 1,2 (relevant to claim 11);
  It is noted that the surface of the safety means adjacent to the trigger means is seen as being the obstructer part of the safety means.

Document D2 (see figures 4,5) discloses all the features of dependent claims 2,3 and 8 to 13.

Document D3 (see figures 1 and 2a to 2c) discloses all the features of dependent claims 2 to 4, 7 and 9 to 11.

Hence, dependent claims 2-4 and 6 to 13 are not allowable for lack of novelty of the subject-matter defined therein (Article 33(2) PCT).

4 Dependent claims 5 and 14 to 18 seem to contain additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT with respect to novelty (Article 33(2) PCT), inventive step (Article 33(3) PCT) or industrial applicability (Article 33(4) PCT).

B Invention II (Claims 19-30):

1 Reference is made to the following document (D):
D2: US 2001/031945 A1.

2 The present application does not meet the requirements of Article 33(2) PCT, because the subject-matter of claim 19 is not new in the sense of Article 33(2) PCT. The reasons are as follows:

2.1 The document D2 is regarded as being the closest prior art to the subject-matter of claim 19, and discloses (the references in parentheses applying to this document):

"A casing (see fig. 4, reference signs 6 and 44) for enclosing a container (see fig. 4, reference sign 23) of a medicament (see fig. 4, reference sign 12) of the type having an opening (see fig. 5, reference sign 20) at one end through which the medicament (see fig. 4, reference sign 12) may be accessed for dispensing and the opening (see fig. 5, reference sign 20) being closed prior to use by a break-off tip (see fig. 4, reference sign 22),

the casing (see fig. 4, reference signs 46 and 44) comprising relatively moveable first and second casing parts (see fig. 4, reference signs 46 and 44), being a first casing part (see fig. 4, reference sign 46) adapted to hold the container (see fig. 4, reference sign 23), and a second part (see fig. 4, reference sign 44) adapted to bear upon the break-off tip (see fig. 4, reference sign 22) of a container (see fig. 4, reference sign 23) held by the first casing part (see fig. 4, reference sign 46) as a result of such relative motion to apply a force thereto causing the break-off tip (see fig. 4, reference sign 22) to break off from the container (see fig. 4, reference sign 23)".

3 Dependent claims 20, 21, 23-26 and 30 do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT with respect to novelty, the reasons being as follows:

3.1 Document D2 discloses all the features of dependent claims 20, 21, 23-26 and 30, see for example:

- figures 4 and 5 (relevant to claims 20 and 21);
- figures 4 and 5, namely:

"a casing" (see fig. 4 and 5, reference signs 44 and 46);
"an injection device" (see fig. 4 and 5);
"a cartridge" (see fig. 4 and 5, reference sign 23);
"a medicament for injection" (see fig. 4 and 5, reference signs 12);
"an orifice" (see fig. 5, reference sign 20);
"drive means" (see fig. 4 and 5, reference signs 37,38,42);
"trigger means" (see fig. 4 and 5, reference sign 36);
"safety means" (see fig. 4 and 5, the inner surface of the casing which covers the trigger means prevents the trigger means from being pushed in the first configuration);

"actuator means" (see fig. 4 and 5, it is the part of the casing which is suitable to be gripped pushed by the hand of an users to bring the safety means from its first configuration (see fig. 4) into its second configuration (see fig. 5));
"first configuration" (see fig. 4);
"second configuration" (see fig. 5)
(relevant to claim 23,24,25,26 and 30);

Hence, dependent claims 20, 21, 23-26 and 30 are not allowable for lack of novelty of the subject-matter defined therein (Article 33(2) PCT).

4 Dependent claims 22 and 27 to 29 seem to contain additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT with respect to novelty (Article 33(2) PCT), inventive step (Article 33(3) PCT) or industrial applicability (Article 33(4) PCT).

C Upon entering the regional phase, the applicant is kindly requested to observe the following:

1 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 are not mentioned in the description, nor are these documents identified therein;

2 When filing amended claims the applicant should at the same time bring the description into conformity with the amended claims in accordance with Rule 5.1(a)(iii) PCT;

3 A new independent claim should be in the two-part form in accordance with Rule 6.3(b) PCT, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterizing part (Rule 6.3(b)(ii) PCT);

4 The features of the claims should be provided with reference signs placed in parentheses (Rule 6.2(b) PCT);

5 According to the requirements of Rule 11.13(m) PCT the same feature shall be denoted by the same reference sign throughout the application. This requirement is not met in view of the use of reference sign "105" which is obviously used for the medicament (see fig. 4 of the application), but on page 13, line 27 this reference sign is also used for the orifice.

6 The following typing errors should be corrected:

US-A-2001/0004681	==>	US-A-2001/004681	(see page 1, lines 27 and 28),
WO-A-97/37750	==>	WO-A-97/37705	(see page 7, lines 15 and 16),
Claim number "33"	==>	Claim number "3"	(see page 21, line 23).

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